



DOCKET NO: I0248.70014US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Wallner  
Serial No: 09/744,658  
Confirmation No: 3397  
Filed: May 30, 2001  
For: REGULATION OF SUBSTRATE ACTIVITY  
Examiner: Jeffrey E. Russel  
Art Unit: 1654

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 24<sup>th</sup> day of August, 2004.

  
Kristin J. Ketelhut

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**MAIL STOP RCE**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. §1.114.

No fee or certification is required.

**PART II: Information Cited**

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
I0248.70012US00	09/578,363	25 May 2000	Wallner et al.
I0248.70013US00	09/290,376	12 April 1999	Wallner
<sup>1</sup> I0248.70016US01	10/879,479	28 June 2004	Wallner et al.
I0248.70024US00	10/616,409	9 July 2003	Adams et al.
<sup>2</sup> I0254.70007US00	09/289,321	9 April 1999	Bachovchin
<sup>3</sup> I0254.70008US00	08/850,542	15 October 1997	Bachovchin
<sup>3</sup> I0254.70008US01	10/775,598	10 February 2004	Bachovchin
<sup>4</sup> I0254.70014US01	10/778,667	13 February 2004	Huber

<sup>1</sup>See US Patent Number 6,770,628, issued 03 August 2004 for an identical specification

<sup>2</sup>See US Patent Number 5,965,532, issued 12 October 1999 for an identical specification

<sup>3</sup>See US Patent Number 5,462,928, issued 31 October 1995 for an identical specification

<sup>4</sup>See US Published Patent Application Number 2003/0212044, published 13 November 2003 for an identical specification

The Applicant would like to bring to the Examiner's attention the enclosed search report or other communication from a corresponding International Application.

<u>Docket No.</u>	<u>Serial No.</u>	<u>Mailing Date</u>	<u>Type of Communication</u>
I0248.70004WO00	PCT/US99/18315	3 February 2000	International Search Report
I0248.70004WO00	PCT/US99/18315	22 May 2000	Written Opinion
I0248.70004WO00	PCT/US99/18315	23 November 2000	International Preliminary Examination Report

The following are remarks concerning the other information cited:

### PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;

2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;

3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.


By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

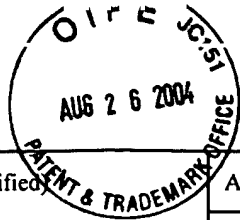
Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
Wallner, *Applicant*

By:   
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Docket No. I0248.70014US00  
Date: August 24 2004  
**XNDDX**



FORM PTO-1449/A and B (Modified)				APPLICATION NO.: 09/744,658		ATTY. DOCKET NO.: I0248.70014US00	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				FILING DATE: May 30, 2001		CONFIRMATION NO.: 3397	
				APPLICANT: Wallner			
				GROUP ART UNIT: 1654		EXAMINER: Jeffrey E. Russel	
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#### U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A1	4,935,493		Bachovchin et al.	06-19-1990
	A2	5,462,928		Bachovchin et al.	10-31-1995
	A3	5,543,396		Powers et al.	08-06-1996
	A4	5,965,532		Bachovchin	10-12-1999
	A5	6,040,145		Huber et al.	03-21-2000
	A6	6,090,786		Augustyns et al.	07-18-2000
	A7	6,100,234		Huber et al.	08-08-2000
	A8	6,258,597	B1	Bachovchin et al.	07-10-2001
	A9	6,300,314	B1	Wallner et al.	10-09-2001
	A10	6,355,614	B1	Wallner	03-12-2002
	A11	6,503,882	B2	Huber et al.	01-07-2003
	A12	6,692,753	B2	Huber et al.	02-17-2004
	A13	6,703,238	B2	Bachovchin et al.	03-09-2004
	A14	6,770,628	B2	Wallner et al.	08-03-2004
	A15	2003/0158114	A1	Wallner et al.	08-21-2003
	A16	2003/0212044	A1	Huber et al.	11-13-2003
	A17	2004/0077601	A1	Adams et al.	04-22-2004
	A18	2004/0152192	A1	Bachovchin et al.	08-05-2004

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	B1	DD	158109		Universitat Halle Wittenberg (DE)	12-29-1982	Y - Only Abstract
	B2	DD	294176	A5	Universitat Halle Wittenberg (DE)	09-26-1991	Y - Only Abstract
	B3	DD	294711	A5	Universitat Halle Wittenberg (DE)	10-10-1991	Y - Only Abstract
	B4	DD	296075	A5	Unviersität Halle Wittenberg (DE)	11-21-1991	Y - Only Abstract
	B5	DE	19834591	A1	Probiodrug Ges Fuer Arzneimitt (DE)	02-03-2000	Y - Only Abstract
	B6	EP	995440	A1	Probiodrug Ges Fuer Arzneimitt (DE)	04-26-2000	Y - Only Abstract
	B7	EP	1084705	A2	Probiodrug Ges Fuer Arzneimitt (DE)	03-21-2001	Y - Only Abstract
	B8	WO	91/16339	A1	New England Medical Center Hospitals, Inc.	10-31-1991	
	B9	WO	93/08259	A2	New England Medical Center Hospitals, Inc.	04-29-1993	

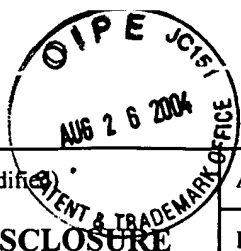


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	B15	WO	97/40832	A1	Hansknöll-Institut Für Naturstoff-Forschung E.V. (DE)	11-06-1997	
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	B17	WO	98/25644	A1	1149336 Ontario, Inc. (CA)	06-18-1998	
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	B20	WO	99/28474	A2	The Government of the United States of America	06-10-1999	
	B21	WO	99/38501	A2	Trustees of Tufts University	08-05-1999	
	B22	WO	99/61431	A1	Probiodrug Gesellschaft Fur Arzneimit Telforschung MBH (DE)	12-02-1999	Y – Only Abstract
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	B24	WO	99/67278	A1	Probiodrug Gesellschaft Fur Arzneimit Telforschung MBH (DE)	12-29-1999	Y – Only Abstract
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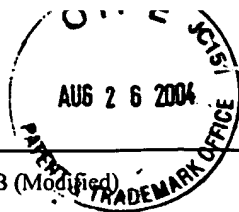
#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C1	AMARA et al., HIV coreceptor downregulation as antiviral principle: SDF-1alpha-dependent internalization of the chemokine receptor CXCR4 contributes to inhibition of HIV replication. J Exp Med. 1997 Jul 7;186(1):139-46.	
	C2	ARENZANA-SEISDEDOS et al., HIV blocked by chemokine antagonist. Nature. 1996 Oct 3;383(6599):400.	
	C3	ATCHISON et al., Multiple extracellular elements of CCR5 and HIV-1 entry: dissociation from response to chemokines. Science. 1996 Dec 13;274(5294):1924-6.	
	C4	BACHOVCHIN et al., Inhibition of IgA1 proteinases from Neisseria gonorrhoeae and Hemophilus influenzae by peptide prolyl boronic acids. J Biol Chem. 1990 Mar 5;265(7):3738-43.	
	C5	BENKIRANE et al., The cytoplasmic tail of CD4 is required for inhibition of human immunodeficiency virus type 1 replication by antibodies that bind to the immunoglobulin CDR3-like region in domain 1 of CD4. J Virol. 1995 Nov;69(11):6904-10.	
	C6	BERSON et al., A seven-transmembrane domain receptor involved in fusion and entry of T-cell-tropic human immunodeficiency virus type 1 strains. J Virol. 1996 Sep;70(9):6288-95.	
	C7	BLEUL et al., The lymphocyte chemoattractant SDF-1 is a ligand for LESTR/fusin and blocks HIV-1 entry. Nature. 1996 Aug 29;382(6594):829-33.	



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C8	BLEUL et al., A highly efficacious lymphocyte chemoattractant, stromal cell-derived factor 1 (SDF-1) J Exp Med. 1996 Sep 1;184(3):1101-9.	
C9	BRISTOL et al., Inhibition of CD26 enzyme activity with pro-boropro stimulates rat granulocyte/macrophage colony formation and thymocyte proliferation in vitro. Blood. 1995 Jun 15;85(12):3602-9.	
C10	BRUBAKER et al., Circulating and tissue forms of the intestinal growth factor, glucagon-like peptide-2. Endocrinology. 1997 Nov;138(11):4837-43.	
C11	BRUBAKER et al., Intestinal function in mice with small bowel growth induced by glucagon-like peptide-2. Am J Physiol. 1997 Jun;272(6 Pt 1):E1050-8.	
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C16	FEIL et al., Endothelial cells differentially express functional CXC-chemokine receptor-4 (CXCR-4/fusin) under the control of autocrine activity and exogenous cytokines. Biochem Biophys Res Commun. 1998 Jun 9;247(1):38-45.	
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C18	HELSELGESSER et al., Identification and characterization of the CXCR4 chemokine receptor in human T cell lines: ligand binding, biological activity, and HIV-1 infectivity. J Immunol. 1998 Jan 15;160(2):877-83.	
C19	HEVEKER et al., Dissociation of the signalling and antiviral properties of SDF-1-derived small peptides. Curr Biol. 1998 Mar 26;8(7):369-76.	
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C21	HOFFMANN et al., Dipeptidyl peptidase IV (CD 26) and aminopeptidase N (CD 13) catalyzed hydrolysis of cytokines and peptides with N-terminal cytokine sequences. FEBS Lett. 1993 Dec 20;336(1):61-4.	
C22	KELLY et al., Immunosuppressive boronic acid dipeptides: correlation between conformation and activity. J Am Chem Soc. 1993; 115(26): 12637-12638.	
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C24	KIM et al., CK beta-11/macrophage inflammatory protein-3 beta/EBI1-ligand chemokine is an efficacious chemoattractant for T and B cells. J Immunol. 1998 Mar 1;160(5):2418-24.	
C25	OBERLIN et al., The CXC chemokine SDF-1 is the ligand for LESTR/fusin and prevents infection by T-cell-line-adapted HIV-1. Nature. 1996 Aug 29;382(6594):833-5. Erratum in: Nature 1996 Nov 21;384(6606):288.	
C26	ORAVECZ et al., Regulation of the receptor specificity and function of the chemokine RANTES (regulated on activation, normal T cell expressed and secreted) by dipeptidyl peptidase IV (CD26)-mediated cleavage. J Exp Med. 1997 Dec 1;186(11):1865-72.	
C27	REINHOLD et al., CD26 mediates the action of HIV-1 Tat protein on DNA synthesis and cytokine production in U937 cells. Immunobiology. 1996 Jan;195(1):119-28.	
C28	SCHALL et al., Human macrophage inflammatory protein alpha (MIP-1 alpha) and MIP-1 beta chemokines attract distinct populations of lymphocytes. J Exp Med. 1993 Jun 1;177(6):1821-6.	
C29	SHIODA et al., Anti-HIV-1 and chemotactic activities of human stromal cell-derived factor 1alpha (SDF-1alpha) and SDF-1beta are abolished by CD26/dipeptidyl peptidase IV-mediated cleavage. Proc Natl Acad Sci U S A. 1998 May 26;95(11):6331-6.	



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	C30	SNOW et al., Studies on Proline Boronic Acid Dipeptide Inhibitors of Dipeptidyl Peptidase IV: Identification of a Cyclic Species Containing a B-N Bond. Am J Chem Soc. 1994; 116(24): 10860-10869.	
	C31	VAN RIJ et al., The role of a stromal cell-derived factor-1 chemokine gene variant in the clinical course of HIV-1 infection. AIDS. 1998 Jun 18;12(9):F85-90. Erratum in: AIDS 2002 Nov 8;16(16):2239.	

EXAMINER	DATE CONSIDERED
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[NOTE - Must provide a copy of any patent, publication, other information listed, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]